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In the United States Patent and Trademark Office

Appellants:	David J. Tyrrell et al.	Docket No.:	16,497
Serial No.:	09/746,888	Group:	3761
Confirmation No.:	9433	Examiner:	J. Webb
Filed:	December 22, 2000	Date:	February 14, 2003

For: ABSORBENT ARTICLES WITH HYDROPHILIC COMPOSITIONS CONTAINING BOTANICALS

Appeal Brief Transmittal Letter

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192, transmitted herewith in triplicate is an Appeal Brief pursuant to the Notice of Appeal which was mailed on January 8, 2003.

Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(c), which is due to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. This Appeal Brief Transmittal Letter is submitted in duplicate.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

By: Alyssa A Dudkowski
Alyssa A. Dudkowski
Registration No.: 40,596

CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell
Cynthia M. Trudell

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For: ABSORBENT ARTICLES WITH HYDROPHILIC COMPOSITIONS CONTAINING BOTANICALS

Brief on Appeal to the Board of Patent Appeals and Interferences

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.192 Appellants respectfully submit this Brief in support of their Appeal of the **Final Rejection** of claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 that was mailed on November 1, 2002. On January 8, 2003, Appellant, pursuant to 37 C.F.R. 1.191 mailed a timely Notice of Appeal which was received in the Patent Office on January 14, 2003. In accordance with 37 C.F.R. 1.192(a) this Appeal Brief is filed in triplicate.

Real Party in Interest

Kimberly-Clark Worldwide, Inc., the assignee of the present patent application, is the real party in interest.

Related Appeals and Interferences

Applicants submit that there <u>are</u> two (2) related Appeals: (1) a Notice of Appeal was also mailed for co-pending application serial number 09/746,880 (also filed on December 22, 2000); and (2) a Notice of Appeal was also mailed for co-pending application serial number 09/746,872 (also filed on December 22, 2000). These three applications pertain to the same general subject matter and the grounds of final rejection/arguments in response are similar. Further, all three applications are before the same Examiner, Examiner Jamisue Webb.

Status of the Claims

Claims 1-57 are pending in the application.

Claims 8, 9, 35, 36, 42, 44 and 48 are withdrawn from consideration.

Claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 stand rejected and form the subject matter of this appeal.

Status of Amendments Filed Subsequent to Final Rejection

An Amendment After Final was submitted on December 2, 2002. By way of an Advisory Action mailed December 24, 2002, the Examiner considered the request for reconsideration but did not find the application to be in condition for allowance.

Summary of the Invention

In one aspect, the present invention is directed to an absorbent article including an outer cover; a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover; and an absorbent body that is located between the bodyside liner and the outer cover. Further, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner. The composition includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active. **(See, for example, claim 1)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds. **(See, for example, claim 20)**

In another aspect of the present invention, the article includes a composition on at least a portion of the bodyfacing surface of the bodyside liner where the composition includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 85 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; **(5)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(6)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(7)** from about 0.1 to about 10 percent by weight of emollient;

and) **(8)** from about 0.1 to about 10 percent by weight of extracted botanical active. **(See, for example, claim 21)** In a further aspect of the present invention, the article includes a composition including the same components and where the extracted botanical active is selected from: echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds. **(See, for example, claim 39)**.

In another aspect, the present invention is directed to a method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article. The method includes a step of heating a composition to a temperature above the melting point of the composition, where the composition includes: **(1)** hydrophilic solvent; **(2)** high molecular weight polyethylene glycol; **(3)** C_{14} to C_{30} fatty alcohol; **(4)** C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds. The composition has a melting point of from about 32°C to about 100°C. The method also includes the steps of applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article and resolidifying the composition. **(See, for example, claim 40)**

In another aspect, the present invention is directed to a method for protecting the skin barrier on a skin surface of a user. The method includes a step of contacting the skin surface of the user with a bodyfacing surface of a liner material. The bodyfacing surface of the liner material includes a composition where the composition includes a hydrophilic solvent, a high molecular weight polyethylene glycol, a C_{14}-C_{30} fatty alcohol, a C_{14}-C_{30} fatty acid and an extracted botanical active. The method also inlcudes a step of maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface. The method further includes a step of repeating contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to protect the skin barrier. More specifically, the composition on the liner material includes: **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 1 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds. **(See, for example, claim 54)**

The Issues Presented

In the First Office Action mailed March 13, 2002, the Examiner rejects claims 1-7, 10-13, 16-20, 40, 41, 43, 45-47, 49, 50 and 52-57 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,238,682 issued to Klofta et al. (hereinafter "the Klofta patent").

The Examiner believes the Krzysik patent discloses an absorbent article including a topsheet, a backsheet and an absorbent core located in between the topsheet and the backsheet. (See Appendix B for portions of the Krzysik patent cited by the Examiner). The Examiner believes the Krzysik patent discloses a lotion composition on the topsheet where the lotion composition is melted, applied to the topsheet and then cooled. The Examiner also believes that the Krzysik patent discloses a lotion composition having a melting temperature of between 30 and 100 degrees Celsius; a low shear viscosity between 50,000 and 80,000 centipoise; a high shear viscosity between 150 and 200 centipoise; a penetration hardness between 5 and 360 mm; and disposition on the topsheet in an amount of 1-50 grams per square meter. The Examiner acknowledges that the Krzysik patent does not disclose a lotion composition including a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty acid, a fatty alcohol and an extracted botanical active.

The Examiner believes the Klofta patent discloses a lotion composition having 5-60% hydrophilic solvent, a high molecular weight polyethylene glycol, 0.1-60% of a skin conditioning agent (such as fatty alcohols and fatty acids) and from 0.1-6% of a botanical active. (See Appendix C for portions of the Klofta patent cited by the Examiner). The Examiner believes it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the composition of the Krzysik patent to be the composition of the Klofta patent in order to provide a lotion composition that kills viruses and imparts a soft lubricious feel.

Also in the First Office Action mailed March 13, 2002, the Examiner rejects claims 14, 15, 21-39 and 51 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,149,934 issued to Krzysik et al. (hereinafter "the Krzysik patent") in view of U.S. Patent No. 6,238,682 issued to Klofta et al. (hereinafter "the Klofta patent") and further in view of U.S. Patent No. 6,316,030 to Kropf et al . (hereinafter "the Kropf patent"). The Examiner acknowledges that the Krzysik and Klofta patents fail to disclose a composition including a sterol. The Examiner believes the Kropf patent discloses a composition containing 0.1-5% sterol. (See Appendix D for portions of the Kropf patent cited by the Examiner) The Examiner believes it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of the Krzysik and Klofta patents to include

the sterol of the Kropf patent in order to provide a caring and protective effect and to increase skin moisture level.

In the Appellants's response mailed June 26, 2002, Appellants respond to the Examiner's rejection of the claims over the combinations of the Krzysik and Klofta patents and the Krzysik, Klofta and Kropf patents.

In the Final Office Action mailed November 1, 2002, the Examiner indicates that she did not find the Appellants's arguments of June 26, 2002 to be persuasive. In response to Appellants' argument that one of ordinary skill in the art would not be motivated to combine the disclosures of a diaper and tissue papers, the Examiner believes the Krzysik patent discloses the use of lotion on a topsheet and that the Klofta patent discloses a lotion that is to mitigate the potential for skin irritation. The Examiner also believes the Krzysik patent discloses to improve skin health and therefore, one of ordinary skill in the art would have motivation to combine the two references. The Examiner was not persuaded by Appellants' arguments that it would be undesirable to use an antibacterial composition on the bodyside liner (a.k.a. topsheet) of a diaper. The Examiner indicated that a subclass of art has been devoted to the use of antibacterial material on topsheets or in contact with a user's skin in diapers or other absorbent articles. With respect to Appellants' arguments that it would not have been obvious to combine the Kropf patent with the Krzysik and Klofta patents, the Examiner believes, due to the fact that the Kropf patent is being used for cosmetics and pharmaceutical preparations, the Kropf patent discloses the pharmaceutical preparations being compositions useful in skin care. The Examiner also believes that the Krzysik and Klofta patents disclose a skin care composition and therefore, one of ordinary skill in the art, when modifying the skin care compositions of the Krzysik and Klofta patents, would look at other skin care compositions, including pharmaceutical preparations.

In the Advisory Action mailed December 24, 2002, the Examiner indicates that she believes the conclusion of obviousness is not based upon improper hindsight reasoning. The Examiner explains that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. The Examiner also explains that so long as the reasoning takes into account only knowledge that was within the level of ordinary skill at the time the invention was made and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. With respect to Appellants' argument that there is no motivation in the Klofta patent to apply the disclosed lotion on a diaper, the Examiner believes the motivation lies in the Krzysik patent. More specifically, the Examiner believes the Klofta patent discloses a lotion used for skin health, the Krzysik patent discloses the use of a diaper with a lotion on it for skin health and therefore, the rejection is based on replacing one lotion for another, both of which are used to improve skin health.

1. Whether claims 1-7, 10-13, 16-20, 40, 41, 43, 45-47, 49, 50 and 52-57 are unpatentable under 35 U.S.C. § 103 over the Krzysik patent in view of the Klofta patent?

A. Specifically, has the Examiner met the burden of establishing a *prima facie* case of obviousness?

1. Has the Examiner met the burden of establishing that there is a suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references and to combine the teachings of the references?

i. Claim Group I: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol; **(3)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active?

2. Has the Examiner met the burden of establishing that there would be a reasonable expectation of success? (Claim Group I)

2. Whether claims 14, 15, 21-39 and 51 are unpatentable under 35 U.S.C. § 103 over the Krzysik patent in view of the Klofta patent and further in view of the Kropf patent?

A. Specifically, has the Examiner met the burden of establishing a *prima facie* case of obviousness?

1. Has the Examiner met the burden of establishing that there is a suggestion or motivation either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references and to combine the teachings of the references?

i. Claim Group II: Has the Examiner shown that the suggestion or motivation exists in the references or in the knowledge generally available to one of ordinary skill in the art to modify the references and to combine the teachings of the references to arrive at an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 80 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 85 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)**

from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; **(5)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(6)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(7)** from about 0.1 to about 10 percent by weight of emollient; and **(8)** from about 0.1 to about 10 percent by weight of extracted botanical active?

2. Has the Examiner met the burden of establishing that there would be a reasonable expectation of success? (Claim Group II)

Grouping of the Claims

For the rejections described in Issue 1:

Group I: Claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57 stand or fall as a group.

Group II: Claims 21-34 and 37-39 stand or fall as a group.

For the rejections described in Issue 2:

Group I: Claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57 stand or fall as a group.

Group II: Claims 21-34 and 37-39 stand or fall as a group.

The rejected claims do not stand or fall together. The claims should be considered in two groups for the reasons provided in the Argument section below.

Argument

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Krzysik patent for modifying its teachings with the teachings of the Klofta patent.

Claim Group I: Claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57 are directed, in part, to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol;

(3) from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 0 to about 40 percent by weight of C_{14} to C_{30} fatty acid; and **(5)** from about 0.1 to about 10 percent by weight of extracted botanical active. Neither of the two cited references (the Krzysik patent and the Klofta patent) discloses the claimed composition applied to a bodyside liner of an absorbent article. The Examiner improperly "picked and choosed" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed March 13, 2002, the Examiner states "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Krzysik to be the composition of Klofta, in order to provide a lotion composition that kills viruses and imparts a soft lubricious feel." In the Final Office Action mailed November 1, 2002, the Examiner states "With respect to applicant's arguments that one of ordinary skill in the art would not be motivated to combine disclosures of a diaper and tissue papers: Krzysik discloses the use of lotion on a topsheet, and Klofta discloses a lotion that is to mitigate the potential for skin irritation, Krzysik discloses to improve skin health, therefore one of ordinary skill in the art would have motivation to combine the two." In the Advisory Action mailed December 24, 2002, the Examiner states "The motivation for a lotion being in a diaper is located already in the Krysik [sic] patent, the Klofta [sic] discloses a lotion used for skin health, Krysik [sic] discloses the use of a diaper with a lotion on it for skin health, therefore the rejection is simply replacing one lotion for another, both of which are used to improve skin health." In the First Office Action, the Final Office Action and the Advisory Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The Examiner does not adequately state why one of ordinary skill would read the Krzysik patent and then look to the Klofta patent and select particular compounds to arrive at the composition of claims 1-7, 10-20, 40-41, 43, 45-47 and 49-57.

Claim Group I includes claims directed, in part, to absorbent articles with compositions including five components: (1) hydrophilic solvent; (2) high molecular weight polyethylene glycol; (3) C_{14} to C_{30} fatty alcohol; (4) C_{14} to C_{30} fatty acid; and (5) extracted botanical active. The Krzysik patent discloses an absorbent article having a lotionized bodyside liner, but as acknowledged by the Examiner, the Krzysik patent does not disclose a lotion composition that includes a hydrophilic solvent, a high molecular weight polyethylene glycol, a fatty acid, a fatty alcohol and an extracted botanical active. (See Office Action mailed March 13, 2002, page 4). The Klofta patent is directed to anhydrous skin lotions having antimicrobial components for application to tissue paper. The Examiner relies on the Klofta patent as disclosing hydrophilic solvents (at col. 5, lines 6-8), a high molecular weight polyethylene glycol (at col. 10, lines 9-10), "skin conditioning agents" such as fatty alcohols and fatty

acids (at col. 18, line 10 to col. 19, line 24) and extracted botanical active (at Col. 16, lines 31-67). (See Appendix C to this Appeal Brief for these portions of the Klofta patent.)

The motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner believes that one of skill in the art would simply replace the lotion of the Krzysik patent with the lotion of the Klofta patent. However, the Examiner does not explain why one of skill in the art would pick and choose components from the Klofta patent to form a lotion for diapers. The portion of the Klofta patent that the Examiner relies on as disclosing "extracted botanical actives" refers to "natural essential oil antibacterial actives include[ing] oils"; the Examiner does not explain why one of ordinary skill in the art would consider this reference to be the same as the "extracted botanical actives" of the invention as they are defined on page 34, line 23 of the Specification as filed. Additionally, the Examiner does not explain why one of skill in the art would select "antibacterial essential oils" from the Klofta patent for the purpose of reducing the skin's irritation response to biological insults. Further, the compositions disclosed by the Klofta patent include components not claimed by the present invention (e.g. "antimicrobials" are the key active ingredients of the Klofta compositions; see Col. 11, lines 16-20). Therefore, one of skill in the art would not be able to simply replace the lotion of the Krzysik patent with a composition from the Klofta patent. The Examiner has failed to identify how the cited references suggest the desirability of modifying the compositions of the Krzysik patent to include components from the Klofta patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of the compositions of Claim Group I from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)[1]. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group I are separately patentable over the references.

[1] "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Krzysik patent for modifying its teachings with the teachings of the Klofta and Kropf patents.

Claim Group II: Claims 21-34 and 37-39 are directed to an absorbent article including a composition on at least a portion of the bodyfacing surface of a bodyside liner where the composition includes **(1)** from about 10 to about 90 percent by weight of hydrophilic solvent; **(2)** from about 5 to about 85 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons; **(3)** from about 1 to about 30 percent by weight of C_{14} to C_{30} fatty alcohol; **(4)** from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7; **(5)** from about 0.1 to about 30 percent by weight of natural fats or oils; **(6)** from about 0.1 to about 10 percent by weight of sterols or sterol derivatives; **(7)** from about 0.1 to about 10 percent by weight of emollient; and **(8)** from about 0.1 to about 10 percent by weight of extracted botanical active. As compared to Claim Group I, the compositions of Claim Group II include the additional components of an emulsifying surfactant having a combined HLB in a range greater than 7, natural fats or oils, sterols or sterol derivatives and an emollient. The Examiner believes the Klofta patent discloses emulsifying surfactants having a combined HLB in a range greater than 7 (at Col. 21, lines 12-14), natural fats or oils (at Col. 27, lines 30-37) and emollients (at Col. 18, lines 10-12) and the Examiner believes the Kropf patent discloses sterols or sterol derivatives (at the Abstract and Col. 3, lines 32-35).

In the Office Action mailed March 13, 2002, the Examiner states "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composition of Krzysik and Klofta, to include the sterol of Kropf, in order to provide a caring and protective effect and increase skin moisture level." In the Final Office Action mailed September 1, 2002, the Examiner states "With respect to Applicant's arguments that it would not have been obvious to combine Kropf with Krzysik and Klofta, due to the fact that Fropf [sic] is being used for cosmetics and pharmaceutical preparations: Kropf discloses the pharmaceutical preparations being compositions useful in skin care. Krysik [sic] and Klofta disclose a skin care composition, therefore One of ordinary skill in the art, when modifying the skin care composition of Krysik [sic] and Klofta, would look at other skin care compositions, which would include pharmaceutical preparations, therefore it is the examiner's position that there would be motivation to combine Kropf with Krysik [sic] and Klofta." In the First Office Action and the Final Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The Examiner does not adequately state why one of ordinary skill would read the Krzysik patent and then look to the Klofta

patent and select particular compounds and then further look to the Kropf patent to select additional particular compounds to arrive at the composition of claims 21-34 and 37-39.

However, for the same reasons as those stated above, the Examiner does not identify how the references suggest the desirability of modifying the Krzysik patent compositions to include these additional components from the Klofta and Kropf patents. For example, the Kropf patent relates to "nanoparticles and more particularly to the use of nanoscale sterols and sterol esters in cosmetics." (See Col. 1, lines 12-14). The Kropf patent does not contain any teaching about using such "nanoscale sterols and sterol esters" in compositions to be applied to absorbent articles. The Examiner's observation that the "nanoscale sterols and sterol esters" of the Kropf patent may be used in pharmaceutical preparations is an insufficient basis for why one of ordinary skill in the art would read the Kropf patent and then think to use the disclosed compounds in a composition for absorbent articles. For at least these reasons, Appellants assert that a *prima facie* case of obviousness has not been made and that the claims of Claim Group II are separately patentable over the references.

3. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the compositions of the Krzysik patent to include components from the Klofta and Kropf patents.

One of the benefits of the compositions of the present invention is their ability to reduce the irritation response of the skin when the skin is exposed to fecal protease and bile acid insults. (See pages 56-64 of the Specification as filed; copy provided as Appendix E to this Appeal Brief). In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor of reducing the irritation response of skin exposed to fecal proteases and bile acids. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success at reducing irritation response. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

The Klofta patent relates to anhydrous skin lotion compositions having antimicrobial components where the lotions tend to be mild to the skin in order to mitigate skin irritation. (See Col. 1, lines 17-25). Because "antimicrobials" tend to be inherently irritating to the skin, the Klofta patent teaches lotions that are formulated to soften the effect of the active ingredient. The Examiner does not explain why one of skill in the art would have been motivated to select the "antibacterial essential oils"

of the Klofta patent to be used in the lotion compositions of the Krzysik patent- particularly in view of the large number of groups of compounds disclosed in the Klofta patent- for the purpose of reducing skin irritation response to fecal proteases and bile acids (particularly when the lotions of the Klofta patent are inherently prone to cause irritation themselves). Therefore, there would have been no expectation of success at arriving at a composition that reduces the irritation response of skin to the enzymes in biological fluids as occurs with the compositions claimed by the present invention. Additionally, none of the cited references recognize the "result-effective" capability of the extracted botanical actives of the present invention.

In view of the above Arguments, it is respectfully submitted that the rejection of claims 1-7, 10-34, 37-41, 43, 45-47 and 49-57 under 35 U.S.C. § 103 are in error. Accordingly, Appellants respectfully request that the Examiner's rejection be reversed. Please charge the $320.00 fee, pursuant to 37 C.F.R. 1.17(f), for filing this Appeal Brief to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. Any additional prosecutional fees which are due may also be charged to deposit account number 11-0875.

The undersigned may be reached at: (920) 721-2433.

Respectfully submitted,

DAVID J. TYRRELL ET AL.

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CERTIFICATE OF MAILING

I, Cynthia M. Trudell, hereby certify that on February 14, 2003 this document is being deposited with the United States Postal Service as first-class mail, postage prepaid, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

By: Cynthia M. Trudell

Cynthia M. Trudell

Appendix A – The Claims On Appeal

1. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 weight percent of a hydrophilic solvent, from about 5 to about 90 percent by weight of a high molecular weight polyethylene glycol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty acid and from about 0.1 to about 10 percent by weight of extracted botanical active.

2. The absorbent article of claim 1, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C.

3. The absorbent article of claim 1, wherein the hydrophilic solvent of the composition is selected from water, propylene glycol, low molecular weight polyethylene glycol, glycerin, hydrogenated starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

4. The absorbent article of claim 1, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 720 to about 1,840,000 daltons.

5. The absorbent article of claim 1, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 1,400 to about 440,000 daltons.

6. The absorbent article of claim 1, wherein the fatty alcohol of the composition is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

7. The absorbent article of claim 1, wherein the extracted botanical active of the composition is selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds.

8. (Withdrawn)

9. (Withdrawn)

10. The absorbent article of claim 1, wherein the composition further includes from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7.

11. The absorbent article of claim 10, wherein the emulsifying surfactant is selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

12. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 30 percent by weight of natural fats or oils.

13. The absorbent article of claim 12, wherein the natural fat or oil is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

14. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives.

15. The absorbent article of claim 14, wherein the sterol or sterol derivative is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

16. The absorbent article of claim 1, wherein the composition further includes from about 0.1 to about 10 percent by weight of emollient.

17. The absorbent article of claim 16, wherein the emollient is selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

18. The absorbent article of claim 1, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier.

19. The absorbent article of claim 18, wherein the rheology modifier is selected from natural clays, synthetic analogs of natural clays, alginates, natural gums and mixtures thereof.

20. An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 weight percent of a hydrophilic solvent, from about 5 to about 90 percent by weight of a high molecular weight polyethylene glycol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty acid and from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds.

21. (Amended) An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 percent by weight of hydrophilic solvent, from about 5 to about 85 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons, from about 1 to about 30 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty acid, from about 1 to about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7, from about 0.1 to about 30 percent by weight of natural fats or oils,

from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 0.1 to about 10 percent by weight of emollient and from about 0.1 to about 10 percent by weight of extracted botanical active.

22. The absorbent article of claim 21, wherein the composition has a melting point from about 32°C to about 100°C.

23. The absorbent article of claim 21, wherein the composition has a high shear viscosity less than about 5,000 centipoise at a temperature greater than about 60°C and has a low shear viscosity greater than about 50,000 centipoise at a temperature of about 55°C..

24. The absorbent article of claim 21, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

25. The absorbent article of claim 21, wherein the composition is on the bodyfacing surface in an amount of from about 0.1 grams per meter squared (g/m2) to about 30 g/m2.

26. The absorbent article of claim 21, wherein the hydrophilic solvent of the composition is selected from water, propylene glycol, low molecular weight polyethylene glycol, glycerin, hydrogenated

starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

27. The absorbent article of claim 21, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 720 to about 1,840,000 daltons.

28. The absorbent article of claim 21, wherein the molecular weight of the high molecular weight polyethylene glycol is from about 1,400 to about 440,000 daltons.

29. The absorbent article of claim 21, wherein the fatty alcohol of the composition is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

30. The absorbent article of claim 21, wherein the emulsifying surfactant of the composition is selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

31. The absorbent article of claim 21, wherein the natural fat or oil of the composition is selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

32. The absorbent article of claim 21, wherein the sterol or sterol derivative of the composition is selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate,

dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

33. The absorbent article of claim 21, wherein the emollient of the composition is selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

34. The absorbent article of claim 21, wherein the extracted botanical active of the composition is selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds.

35. (Withdrawn)

36. (Withdrawn)

37. The absorbent article of claim 21, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier.

38. The absorbent article of claim 37, wherein the rheology modifier is selected from natural clays, synthetic analogs of natural clays, alginates, natural gums and mixtures thereof.

39. (Amended) An absorbent article comprising:

(a) an outer cover;

(b) a liquid permeable bodyside liner that defines a bodyfacing surface and that is connected in superposed relation to the outer cover;

(c) an absorbent body that is located between the bodyside liner and the outer cover; and

(d) a composition on at least a portion of the bodyfacing surface of the bodyside liner that includes from about 10 to about 90 percent by weight of hydrophilic solvent, from about 5 to about 95 percent by weight of high molecular weight polyethylene glycol having a molecular weight of at least about 720 daltons, from about 1 to about 30 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 0 to about 40 percent by weight of a C_{14} to C_{30} fatty acid, from about 1 to

about 10 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7, from about 0.1 to about 30 percent by weight of natural fats or oils, from about 0.1 to about 10 percent by weight of sterols or sterol derivatives, from about 0.1 to about 10 percent by weight of emollient and from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds.

40. A method of applying a composition to a bodyfacing surface of a bodyside liner of an absorbent article comprising the steps of:

(a) heating a composition comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a C_{14} to C_{30} fatty alcohol, a C_{14} to C_{30} fatty acid and from about 0.1 to about 10 percent by weight of extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds, to a temperature above the melting point of the composition, the composition having a melting point of from about 32° C to about 100° C;

(b) applying the composition to the bodyfacing surface of a bodyside liner of an absorbent article; and

(c) resolidifying the composition.

41. The method of claim 40, wherein after the step of resolidification, the composition has a low shear viscosity of greater than about 50,000 centipoise.

42. (Withdrawn)

43. The method of claim 40, wherein after the step of heating, the composition is applied by slot coating.

44. (Withdrawn)

45. The method of claim 40, wherein the hydrophilic solvent of the composition is from about 10 to about 90 percent by weight of the composition and is selected from water, propylene glycol, low molecular weight polyethylene glycol, glycerin, hydrogenated starch hydrolysate, methoxyisopropanol, PPG-2 propyl ether, PPG-2 butyl ether, PPG-2 methyl ether, PPG-3 methyl ether, dipropylene glycol propyl ether, dipropylene glycol butyl ether, dipropylene glycol, methyl propanediol, propylene carbonate, water soluble/dispersible polypropylene glycols, ethoxylated polypropylene glycol, sorbitol, silicone glycols and mixtures thereof.

46. The method of claim 40, wherein the high molecular weight polyethylene glycol is from about 5 to about 90 percent by weight of the composition and is selected from polyethylene glycols having a molecular weight of from about 720 to about 1,840,000 daltons.

47. The method of claim 40, wherein the fatty alcohol of the composition is from about 0 to about 40 percent by weight of the composition and is selected from cetyl alcohol, stearyl alcohol, arachidyl alcohol, behenyl alcohol and mixtures thereof.

48. (Withdrawn)

49. The method of claim 40, wherein the composition further includes from about 1 to about 20 percent by weight of emulsifying surfactant having a combined HLB in a range greater than 7 selected from glyceryl stearate SE, glycol stearate SE, water dispersible metal soaps, polysorbate 20, polysorbate 40, polysorbate 60, polysorbate 80 and mixtures thereof.

50. The method of claim 40, wherein the composition further includes from about 0.1 to about 30 percent by weight of natural fats or oils selected from Avocado Oil, Apricot Oil, Babassu Oil, Borage Oil, Camellia Oil, Canola Oil, Castor Oil, Coconut Oil, Corn Oil, Cottonseed Oil, Evening Primrose Oil, Hydrogenated Cottonseed Oil, Hydrogenated Palm Kernel Oil, Maleated Soybean Oil, Meadowfoam Oil, Palm Kernel Oil, Peanut Oil, Rapeseed Oil, Safflower Oil, Sphingolipids, Sweet Almond Oil, Tall Oil, Lauric Acid, Palmitic Acid, Stearic Acid, Linoleic Acid, Stearyl Alcohol, Lauryl Alcohol, Myristyl Alcohol, Benenyl Alcohol, Rose Hip Oil, Calendula Oil, Chamomile Oil, Eucalyptus Oil, Juniper Oil, Sandlewood Oil, Tea Tree Oil, Sunflower Oil, Soybean Oil and mixtures thereof.

51. The method of claim 40, wherein the composition further includes from about 0.1 to about 10 percent by weight of sterols or sterol derivatives selected from cholesterol, sitosterol, stigmasterol, and ergosterol, as well as, C10-C30 cholesterol/lanosterol esters, cholecalciferol, cholesteryl hydroxystearate, cholesteryl isostearate, cholesteryl stearate, 7-dehydrocholesterol, dihydrocholesterol, dihydrocholesteryl octyldecanoate, dihydrolanosterol, dihydrolanosteryl octyldecanoate, ergocalciferol, tall oil sterol, soy sterol acetate, lanasterol, soy sterol, avocado sterols, sterol esters and mixtures thereof.

52. The method of claim 40, wherein the composition further includes from about 0.1 to about 10 percent by weight of emollient selected from petroleum based oils, petrolatum, mineral oils, alkyl dimethicones, alkyl methicones, phenyl silicones, alkyl trimethylsilanes, dimethicone, lanolin, fatty alcohols and mixtures thereof.

53. The method of claim 40, wherein the composition further includes from about 0.5 to about 10 percent by weight of a rheology modifier selected from natural clays, synthetic analogs of natural clays, alginates, natural gums and mixtures thereof.

54. A method for protecting the skin barrier on a skin surface of a user, comprising the steps of:

a) contacting the skin surface of the user with a bodyfacing surface of a liner material, the bodyfacing surface having a composition comprising a hydrophilic solvent, a high molecular weight polyethylene glycol, a C_{14}-C_{30} fatty alcohol, a C_{14}-C_{30} fatty acid and an extracted botanical active;

b) maintaining the bodyfacing surface in contact with the skin surface for a sufficient amount of time to transfer the composition to the skin surface; and

c) repeating the contact of the skin surface with the bodyfacing surface of the liner material for a sufficient period of time to protect the skin barrier,

wherein the composition comprises from about 10 to about 90 percent by weight of hydrophilic solvent, from about 5 to about 90 percent by weight of high molecular weight polyethylene glycol, from about 1 to about 40 percent by weight of a C_{14} to C_{30} fatty alcohol, from about 1 to about 40 percent by weight of a C_{14} to C_{30} fatty acid and from about 0.1 to about 10 percent by weight of an extracted botanical active selected from echinacea, yucca, tumeric, licorice, oat extract, willow herb, spirulina, strontium chloride, green tea, black tea, oolong tea, Chinese tea, tea components and mixtures of such compounds.

55. The method of claim 54, wherein the composition has a melting point from about 32°C to about 100°C.

56. The method of claim 54, wherein the composition has a high shear viscosity of less than about 5,000 centipoise at a temperature of greater than about 60°C and has a low shear viscosity of greater than about 50,000 centipoise at a temperature of about 55°C.

57. The method of claim 54, wherein the composition has a penetration hardness of from about 5 millimeters to about 365 millimeters at 25°C.

Appendix B

Portions of the Krzysik patent cited by the Examiner:

Col. 13, line 64 to Col. 14, line 3:

For example, the lotion formulation may be applied to the bodyside liner **34** by (a) heating the lotion formulation to a temperature above the melting point of the formulation, causing the formulation to melt, (b) uniformly applying the

melted formulation to the bodyfacing surface **52** of the bodyside liner **34**; and (c) resolidifying the deposits of the melted formulation. Desirably, resolidification of the deposits occurs almost instantaneously, without the need for external cooling means such as chill rolls. This can occur if the formulation is heated to a temperature only slightly above or at the melting point of the formulation. However,

Col. 12, lines 31-34:

Moreover, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may define a melting point of from about 30° C. to about 100° C., desirably from about 35° C. to about 80° C., and more desirably from about 40° C. to about 75° C. Lotion formulations which have lower melting points exhibit migration of the lotion during use and at elevated

Col. 12, lines 42-60:

The lotion formulation of the present invention may further define a melt point viscosity of from about 50 to about 1000000 centipoise, desirably from about 50000 to about 800000 centipoise, and more desirably from about 100000 to about 500000 centipoise for reduced migration and improved transfer to the skin of the wearer. Lotion formulations which have lower melt point viscosities exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher melt point viscosities may be so solid as to also exhibit a reduced transfer to the skin.

Further, to provide the improved stability and transfer to the skin of the wearer, the lotion formulation of the present invention may also define a viscosity of from about 50 to about 10000 centipoise, desirably from about 100 to about 500 centipoise, and more desirably from about 150 to about 250 centipoise at a temperature of 60° C. Lotion formulations which have lower viscosities at 60° C. exhibit migration of the lotion through the bodyside liner **34** into the absorbent body **26** of the article which can undesirably result in reduced transfer to the skin. Whereas, lotion formulations which have higher viscosities at 60° C. may be so solid as to also exhibit a reduced transfer to the skin.

Col. 12, lines 66-67

to also exhibit a reduced transfer to the skin.

The penetration hardness of the lotion formulations of this invention can be from about 5 to about 360 millimeters,

Col. 13, lines 44-49

The lotion formulation can be applied to the bodyside liner **34** at any add-on level which provides the desired transfer benefit. For example, the total add-on level of the lotion formulation can be from about 0.05 to about 100 mg/cm^2, desirably from about 1 to about 50 mg/cm^2 and more desirably from about 10 to about 40 mg/cm^2 for improved performance. The add-on amount will depend upon the desired effect of the lotion on the product attributes and the specific lotion formulation. As discussed above, the improved stability and reduced tendency to migrate of the

Appendix C

Portions of the Klofta patent cited by the Examiner as disclosing: "a lotion composition with a 5-60% hydrophilic solvent, a high molecular weight polyethylene glycol [and] 0.1-60% skin conditioning agent such as a fatty alcohols and fatty acids."

Col. 5, lines 6-8 ("hydrophilic solvent"):

Optionally, an inorganic acid may be added in conjunction with the organic acid to adjust pH. The optional inorganic acid may comprise from about 0.1% to 5% of the lotion composition.

The antibacterial component of the lotion comprises from about 0.1% to 6% of the lotion composition. The hydrophilic solvent which comprises from about 5% to 60% of the lotion composition, preferably has from about 1 to 150 carbon atom(s) wherein the carbon atom(s) are either branched or straight chained, saturated or unsaturated, with or without ether linkages and contains from about 1 to 302 hydroxyl group(s).

Col. 10, lines 9-10 ("high molecular weight polyethylene glycol"):

lotion compositions can have the appearance of a semi-solid but can be made to flow as the shear rate is increased. This is due to the fact that, while the semisolid or solid lotion compositions contain primarily solid components, they may also include some minor liquid components.

The solid or semisolid consistency of the lotions at room temperature are due to the addition of high melting components such as those high melting organic acids having antiviral functionality; fatty alcohols; waxes; high molecular weight polyethylene glycols; polyoxyethylene mono-, di-, and tri-sorbitan alkylates; mono-, di-, and tri- sorbitan alkylates; and non-ionic ethoxylated surfactants. The high melting and higher molecular weight alkane fraction of petrolatum, which may be used as a skin conditioning agent in the present invention, can also contribute to raising the melting point of these lotions. These higher molecular weight components of petrolatum are typically high molecular weight waxy-type hydrocarbons.

Col. 18, line 10 to Col. 19, line 24 ("fatty alcohols and fatty acids"):

Skin conditioning agents useful in the present invention can be petroleum-based such as mineral oil and petrolatum, fatty acid ester type, fatty alcohol type, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures of these skin conditioning agents. Suitable petroleum-based skin conditioning agents include those hydrocarbons, or mixtures of hydrocarbons, having chain lengths of from 16 to 32 carbon atoms. Petroleum based hydrocarbons having these chain lengths include mineral oil (also known as "liquid petrolatum") and petrolatum (also known as "mineral wax," "petroleum jelly" and "mineral jelly"). Mineral oil usually refers to less viscous mixtures of hydrocarbons which are liquids at room temperature. Petrolatum usually refers to more viscous mixtures of hydrocarbons having from 16 to 32 carbon atoms. Petrolatum is a particularly preferred skin conditioning agent for lotion compositions of the present invention because of its exceptional skin moisturizing benefits.

Dimethicones and functionalized derivatives of dimethicones are also very effective paper softeners. The amino-functional polydimethylsiloxanes are especially effective softeners for paper. Dimethicones possessing a viscosity range of about 20 to 12,500 centistokes at 25° C. are preferred. Thus, not only could a material such as dimethicone or the other skin conditioning agents mentioned above provide a soft feel to the paper and skin, but they could provide a skin protectant benefit if transferred to the skin. This benefit would be particularly advantageous if it was desirable to prevent a particularly harsh ingredient from contacting the skin.

Fatty alcohols are also particularly preferred due to their crystalline linear structure. The high melt points of the fatty alcohols raises the melt point of the lotion and thus aids in preventing migration of the lotion throughout the fiber network. The linear structure of the fatty alcohols gives the lotion crystalline attributes and should lead to faster crystallization/solidification onto the paper substrate surface. Thus, during application to the paper surface, the lotion should set up and solidify faster on the surface of the paper substrate. This concentrates the lotion at the surface and gives the lotioned paper product a superior feel and also leads to a more efficient use of the antimicrobial(s). The hydroxyl group in the fatty alcohol may also contribute to the lotion's antimicrobial action.

Suitable fatty acid ester type skin conditioning agents include those derived from C_{12}–C_{28} fatty acids, preferably C_{16}–C_{22} saturated fatty acids, and short chain (C_1–C_8, preferably C_1–C_3) monohydric alcohols. Representative examples of such esters include methyl palmitate, methyl stearate, isopropyl laurate, isopropyl myristate, isopropyl palmitate, ethylhexyl palmitate and mixtures thereof. Suitable fatty acid ester skin conditioning agents can also be derived from esters of longer chain fatty alcohols (C_{12}–C_{28}, preferably C_{12}–C_{18}) and shorter chain fatty acids e.g., lactic acid, such as lauryl lactate and cetyl lactate.

In addition to the petroleum-based skin conditioning agents, dimethicone based skin conditioning agents, fatty acid ester skin conditioning agents, and fatty alcohol skin

conditioning agents, the skin conditioning agents useful in the present invention can include minor amounts (e.g., up to about 10% of the total skin conditioning agent) of other, conventional skin conditioning agents. These other, conventional skin conditioning agents include propylene glycol, glycerin, hexylene glycol, polyethylene glycols, triethylene glycol, liposomes, spermaceti, squalene, cholesteryl, or other waxes (such as the C_{12} to C_{50} waxes), fatty acids, and fatty alcohol ethers having from 12 to 28 carbon atoms in their fatty chain, such as stearic acid, propoxylated fatty alcohols; glycerides, acetoglycerides, and ethoxylated glycerides of C_{12}–C_{28} fatty acids; other fatty esters of polyhydroxy alcohols; lanolin and its derivatives; silicone polyether copolymers, and polysiloxanes such as amino-functional polydimethylsiloxanes having a viscosity at 20° C. of from about 5 to about 2,000 centistokes such as disclosed in U.S. Pat. No. 5,059,282, issued to Ampulski et al. on Oct. 22, 1991, which is incorporated by reference.

The amount of skin conditioning agent that can be included in the lotion composition will depend on a variety of factors, including the particular skin conditioning agent involved, the lotion-like benefits desired, the other components in the lotion composition and like factors. The lotion composition can comprise from about 0.1% to about 60% of the skin conditioning agent, more preferably from about 5% to about 50%.

Col. 16, lines 31-67 ("extracted botanical extract"):

Coco phosphatidyl PG-dimonium chloride

Another class of antibacterials, which are useful in the present invention, are the so-called "natural" antibacterial actives, referred to as natural essential oils. These actives derive their names from their natural occurrence in plants. Typical natural essential oil antibacterial actives include oils of anise, lemon, orange, rosemary, wintergreen, thyme, lavender, cloves, hops, tea tree, citronella, wheat, barley, lemongrass, cedar leaf, cedarwood; cinnamon, fleagrass, geranium, sandalwood, violet, cranberry, eucalyptus, vervain, peppermint, gum benzoin, basil, fennel, fir, balsam, menthol, ocmea origanum, *Hydastis carradensis, Berberidaceae daceae,* Ratanhiae and *Curcuma longa.* Also included in this class of natural essential oils are the key chemical components of the plant oils which have been found to provide the antimicrobial benefit. These chemicals include, but are not limited to anethol, catechole, camphene, carvacol, eugenol, eucalyptol, ferulic acid, famesol, hinokitiol, tropolone, limonene, menthol, methyl salicylate, thymol, terpineol, verbenone, berberine, ratanhiae extract, caryophellene oxide, citronellic acid, curcumin, nerolidol and geraniol.

Additional active agents are antibacterial metal salts. This class generally includes salts of metals in groups 3b-7b, 8 and 3a-5a. Specifically are the salts of aluminum, zirconium, zinc, silver, gold, copper, lanthanum, tin, mercury, bismuth, selenium, strontium, scandium, yttrium, cerium, praseodymiun, neodymium, promethum, samarium, europium, gadolinium, terbium, dysprosium, holmium, erbium, thulium, ytterbium, lutetium and mixtures thereof.

Preferred antibacterials for use herein are the broad spectrum actives selected from the group consisting of TRICLOSAN®, TRICLOCARBAN®, OCTOPIROX®, PCMX, ZPT, natural essential oils and their key ingredients, and mixtures thereof. The most preferred antibacterial active for use in the present invention is TRICLOSAN®.

The antibacterial component comprises from about 0.1% to 6% of the lotion composition, preferably from about 0.3%

Col. 21, lines 12-14 ("surfactant with an HLB value of greater than 7"):

while others are not.

Suitable nonionic surfactants will be substantially nonmigratory after the lotion composition is applied to the tissue paper web and will typically have HLB values in the range of from about 4 to about 20, preferably from about 7 to about 20. To be nonmigratory, these nonionic surfactants will typically have melt temperatures greater than the tempera-

Col. 27, lines 30-37 ("natural fats or oils"):

employed in appropriate amounts in the lotion compositions of the present invention. In addition, natural essential oils such as camphor, thymol, pine oil, menthol, eucalyptol (cineole), geraniol, lemon oil, methyl salicylate, clove and other similar materials may be used to give the product a medicinal scent. In addition, some of these natural essential oils also possess antiviral and antibacterial properties. These other optional components may comprise from about 0.1% to 20% of the lotion composition.

Col. 18, lines 10-12 ("emollients"):

This would likely have a negative impact on the tensile and caliper properties of the lotioned paper. However, minor or trace quantities of water in the skin conditioning agent that are picked up as a result of, for example, ambient humidity can be tolerated without adverse effect. Typically, the skin conditioning agents used in the present invention contain about 5% or less water, preferably about 1.0% or less water, more preferably about 0.5% or less water, and most preferably about 0.1% or less water.

Skin conditioning agents useful in the present invention can be petroleum-based such as mineral oil and petrolatum, fatty acid ester type, fatty alcohol type, dimethicones including functionalized derivatives of dimethicones, polyethylene glycols, or mixtures of these skin conditioning agents.

Appendix D

Portions of the Kropf patent cited by the Examiner.

Abstract:

(57) **ABSTRACT**

A composition containing an effective amount of nanoparticles selected from the group consisting of nanoscale sterols, nanoscale sterol esters, and mixtures thereof.

17 Claims, No Drawings

Col. 3, lines 32-35:

application. The nanoscale compounds are normally used in a quantity of 0.1 to 5% by weight, preferably in a quantity of 0.5 to 3% by weight and more preferably in a quantity of 1 to 2% by weight, based on the preparations.

Cosmetic and/or Pharmaceutical Preparations

The preparations obtainable using the nanoscale sterols and sterol esters in accordance with the invention, such as for example hair shampoos, hair lotions, foam baths, cremes, lotions or emollients, may contain mild surfactants, oils, emulsifiers, superfatting agents, pearlescing waxes, stabilizers, consistency regulators, thickeners, polymers, silicone compounds, biogenic agents, deodorizers, anti-dandruff agents, film-formers, preservatives, hydrotropes, solubilizers, sun (UV) protection factors, antioxidants, insect repellents, self-tanning agents, perfume oils, dyes and the like as further auxiliaries and additives.

Appendix E – Pages 56-64 of the Specification as filed.

In order to evaluate the efficacy of the compositions of the invention, a human skin culture was selected to model the response of the human epidermis. EPIDERM skin culture is a cornified, air-interfaced human skin culture. EPIDERM skin culture has multiple layers of progressively differentiated keratinocytes resembling human epidermis. EPIDERM EPI-200 skin culture can be purchased from MatTek Corporation of Ashland, MA. Experiments using EPIDERM skin culture are conducted in six well plates. Typically, five EPIDERM skin culture inserts are added to five of the six wells. Each well contains one milliliter of pre-warmed media that is the same as the EPIDERM skin culture media. The plates are then incubated in a 37°C, 5% CO_2 incubator for thirty minutes. After incubation, 15 microliters of test composition or control are applied to the surface of the EPIDERM skin culture after removing any residual media. The well plates, with the test compositions/control applied, are incubated in the 37°C, 5% CO_2 incubator for thirty minutes after which the underlying media is removed and replaced with fresh, pre-warmed media. Next, ten microliters of insult solution, either fecal protease or bile acid, are applied to the surface of the EPIDERM skin culture.

The insult solution is prepared by diluting a 10 mg/ml stock solution in phosphate-buffered saline to a working concentration of 250 g/ml. The base of the stock solution is 50 mM NaOAcetate, pH 5.5 and 0.15 M NaCl stored at -80°C. One milliliter of the stock protease insult solution contains 2558 USP units of trypsin and 298 USP units of chymotrypsin and is available from Specialty Enzymes, Inc. of Chino, CA. The bile acid insult solution can be prepared by dissolving 65 mg of cholic acid, 62 mg of deoxycholic acid and 31 mg of chenodeoxycholic acid in 10 ml of phosphate-buffered saline. The bile acid insult components can be purchased from Sigma Chemical Co. of St. Louis, MO. Phosphate-buffered saline, pH 7.4 (hereinafter "PBS") can be purchased from Life Technologies of Rockville, Maryland.

Infant feces contain proteases that include trypsin and chymotrypsin (See Haverback, B. J., Dyce, B.J., Gutentag, P.J., and Montgomery, D. W. (1963) Measurement of Trypsin and Chymotrypsin in Stool. Gasteroenterology 44:588-597; and Barbero, G.J., Sibinga, M.S., Marino, J. M., and Seibel, R. (1966) Stool Trypsin and Chymotrypsin. Amer. J. Dis. Child 112:536-540). For internal studies, infant feces were collected and the amount of total protease and trypsin activities determined for each of the fecal extracts. To prepare the extract, the feces were suspended in water and vigorously vortexed. After vortexing, the samples were held on ice prior to centrifugation at 15,000 times the force of gravity for 20 minutes. The supernatant was filtered through 0.22 micron cellulose acetate filters and stored at -80°C until use. The amount of trypsin activity in the fecal extracts ranged from 0.4-402 μg/ml (n=19) as measured by the ability

of the sample to hydrolyze a fluorescently-labeled trypsin peptide substrate (Boc-Gln-Ala-Arg-AMC HCl, BACHEM California, Incorporated, Torrance, CA). Total protease activity was measured as the ability of the sample to hydrolyze a fluorescent dye-labeled casein substrate (EnzChek Protease Assay Kit (E-6639), Molecular Probes, Eugene, OR). Irritation induced in the EPIDERM skin culture correlated with the total protease as well as trypsin activities of the fecal extracts. Based on the literature sources as well as internal data, a trypsin-chymotrypsin insult was chosen as representative of a fecal insult, specifically a fecal protease insult, for the examples that follow.

After application of the insult solution, the well plates are incubated for six hours in the 37°C, 5% CO_2 incubator. At the end of six hours, the well plates are removed from the incubator, the underlying media is removed and stored at -80°C. The response of the EPIDERM skin culture to the test compositions/control and the insult solution is determined by measuring the amount of interleukin-1 alpha (hereinafter "IL-1 "). Interleukin-1 alpha can be quantified using an Interleukin-1 alpha Quantikine Kit available from R&D Systems of Minneapolis, Minnesota. Interleukin-1 alpha measurements are converted to Log_{10} for each of the treatments and the averages for each treatment are calculated. In order to determine the ability of the test compositions to reduce skin irritation caused by the biological insults, the percent mean reduction of IL-1 is calculated as follows:

$$\%\ \text{mean reduction of IL-1} = 100 \times \frac{\text{((control + insult) result - (test composition + insult) result)}}{\text{((control + insult) result - (control + PBS) result)}}$$

(Test composition + insult) result = the measured amount of IL-1 from treatment with a test composition + insult.

(Control + insult) result = the measured amount of IL-1 from a treatment with water or PBS + insult.

(Control + PBS) result = the measured amount of IL-1 from a treatment with water or PBS + PBS.

The greater the % mean reduction of IL-1 , the more effective a composition is at reducing irritation caused by the biological insult (proteases or bile acids).

In order to insure that the test compositions/control do not affect the viability of the EPIDERM skin culture, a MTT assay is run. The MTT dye is taken up by the cells. The reduction of the dye as a result of cellular metabolism can be used to measure the

cytotoxicity of the test compositions. In order to confirm viability, inserts of the EPIDERM skin culture that have already been subjected to the test compositions and biological insults are removed from their media and are washed consecutively through immersion in three different beakers of PBS. Fresh PBS is used for each test composition or control being evaluated. The PBS is discarded onto paper towel. The EPIDERM skin culture inserts are then patted onto paper towel and placed into the wells of a 24 well plate containing 300 microliters of pre-warmed media. After all of the EPIDERM skin culture inserts are washed, they are transferred to new 24 well plates containing 300 microliters of the MTT reagent. The MTT reagent is thiazolyl blue having the formula 3-[4,5-Dimethylthiazol-2-yl]-2,5-diphenyltetrzoliumbromide. The plates are incubated for 2 hours in a 37°C, 5% CO_2 incubator. After incubation, the EPIDERM skin culture inserts are transferred to 24 well plates and are immersed in 2 milliliters of MTT extraction buffer. The extraction buffer extracts the MTT reagent from the cells. The 24 well plates are parafilmed, covered and placed in ZIPLOCK bags to reduce evaporation of the extraction buffer. The covered plates are rocked overnight in the dark. Following overnight rocking, the liquid in the EPIDERM skin culture inserts is decanted back into the wells. The contents of each well are mixed and a 200 microliter aliquot is then removed from each well and transferred to a 96 well plate. The optical density (OD) of the samples is measured at 570 nm using a spectrophotometer. Five hundred seventy nanometers is the optimal wavelength at which to measure the reduced form of MTT reagent. This reading is subtracted from a background reading at 650 nm to improve data quality. Percent viability of each test composition + insult relative to the control + PBS is recorded as the Mean $OD_{\text{test composition + insult}}$ divided by the Mean $OD_{\text{control + PBS}}$; the quotient then multiplied by 100.

EPIDERM skin culture studies were conducted to measure the reduction in IL-1 response between compositions of the invention and a fecal protease-induced irritation. The studies were conducted using botanicals that are representative of the invention. The EPIDERM skin culture studies and associated MTT assays were conducted as already described herein and the results are as reported in Table 2 below.

Table 2.

Botanical Component of Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
1% Echinacea	20% (5) ; 39% (10)*	89% ; 90%
10% Echinacea	22% (5) ; 31% (10)*	80% ; 86%
1% Yucca	27% (5)* ; 54% (10)*	84% ; 95%
10% Yucca	21% (5) ; 18% (10)	83% ; 81%
1% Spirulina	28% (5) ; 29% (10)* ; 12% (5)	84.% ; 81% ; 86%
10% Spirulina	43% (5) ; 12% (10) ; 27% (5)	87% ; 86% ; 92%
1% Tumeric	10% (10)	82%
10% Tumeric	19% (10)	90%
1% Licorice	29% (10)	87%
10% Licorice	9% (10)	80%
1% Oat Extract	6% (10)	81%
10% Oat Extract	14% (10)	82%
1% Willow Herb	8% (10) ; 38% (5)	74% ; 98%
10% Willow Herb	81% (10)* ; 99% (4)*	92% ; 103%
1% Strontium Chloride	0% (10)	85%
10% Strontium Chloride	15% (10)	82%
0.4% Epigallocatechin gallate (component of green tea)	77% (5)* ; 71% (10)* ; 50% (5)	103% ; 101% ; 112%

"*" indicates the composition had a significant mean difference from the PBS + protease insult applying a Student's t-test with $p<0.05$.

The IL-1 reduction results of Table 2. show that the compositions of the invention provide a skin protectant effect as evidenced by a reduced irritation response. At least one set of experiments were conducted for each botanical and, for some botanicals, more than one set of experiments was conducted. The values in parentheses indicate the number of replicates. All botanicals were received as solutions and diluted with PBS (v/v) to desired dilutions (1 and 10%) while strontium and epigallocatechin gallate were weighed out and dissolved in PBS to desired levels (w/v). The sources of the botanicals were as follows: Echinacea from Bio-Botanica; Yucca Glauca from Brooks; Spirulina from Bio-Botanica; Tumeric from Unilever Indonesia; Licorice from Cosmetochem; Oat Extract from Canamino; Willow Herb from Fytokem; Strontium Chloride from Aldrich; and Epigallocatechin Gallate from Sigma Chemical Company.

The reduction of IL-1 results were analyzed to statistically identify "outlier" results. The EPIDERM skin culture is known to be variable with the variability attributed to

differences in the culture, variation in the application of treatment and other uncontrollable factors. A statistical analysis technique was applied to identify when a result abnormally deviated from the rest of the data set. The irritation values were first converted to Log10 in order to make them more Gaussian (bell curve-shaped). After conversion, the values were analyzed for high or low value outliers; subsequently, the values were analyzed with a student's t-test to identify significant differences from the "control". The statistical analysis used to identify "outliers" is described on page 460 of the book, "Statistical Methods in Research and Production" edited by Owen L. Davies and Peter L. Goldsmith, published by Longman Group Limited, fourth revised edition published in 1984.

A separate series of experiments were conducted on green tea extracts and components of green teas. The EPIDERM skin culture tests described in Table 3. below were conducted according to the procedure previously described herein. The number of replicates for each experiment is identified in parentheses after the mean reduction values. The trypsin-chymotrypsin insult solution was applied to the culture wells in an amount of 2.5 g at a concentration of 250 g/ml. The green tea extract and the green tea components were dissolved in phosphate-buffered saline (PBS) to the desired concentrations.

Table 3.

Extracted Botanical Active	Concentration of Extracted Botanical Active	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
Green Tea Extract	4 mg/ml	40% (6) *	Not Available
Green Tea Extract	8 mg/ml	57% (5) *	Not Available
Epicatechin	4 mg/ml	24% (5)	111%
Epigallocatechin	4 mg/ml	30% (5)	125%
Epicatechin gallate	4 mg/ml	62% (5) *	143%
Epigallocatecin gallate	4 mg/ml	73% (4)*; 100% (5)*	Not Available ; 126%

"*" indicates the composition had a significant mean difference from the PBS + protease insult applying a Student's t-test with $p<0.05$.

The green tea extract is available in solid form from DRAGOCO of Totowa, New Jersey. The green tea components are available from Sigma Chemical of St. Louis, Missouri. The results of Table 3. suggest that green tea extract and components of green tea are effective at reducing the skin's irritation response to protease insults, such as those that

may be part of biological insults contained by absorbent articles. These results were also subjected to the statistical outlier analysis.

An additional set of EPIDERM skin culture experiments was conducted to predict the effect of extracted botanical actives on the irritation response to a protease and bile acid insult. The method for utilizing the EPIDERM skin culture described above was also used for this set of experiments evaluating response to a protease and bile acid insult. The EPIDERM skin culture was pretreated with 15 l of test composition containing 4 mg/ml of epigallocatecin gallate in water for a period of 30 minutes in a 37°C/5% CO_2 incubator. The skin culture wells were then treated with 10 l of a protease and bile acid insult for 6 hours under the same incubation conditions. Phosphate-buffered saline solution of pH 7.4 was used as a negative control. After 6 hours, the underlying media is removed and stored at -80°C. The amount of IL-1 from the media was quantified using an Interleukin-1 alpha Quantikine Kit available from R&D Systems of Minneapolis, Minnesota. The protease and bile acid insult was prepared by mixing equal volumes of a bile acid insult with a protease insult. The bile acid insult included 13 mg/ml cholic acid (sodium salt), 12.4 mg/ml deoxycholic acid (sodium salt) and 6.2 mg/ml chenodeoxycholic acid (sodium salt) prepared in pH 7.4 phosphate-buffered saline. The protease insult included 400 g/ml of a trypsin-chymotrypsin mix (Specialty Enzymes of Chino, California) diluted from a stock concentration of 10 mg/ml in 50 mM sodium acetate; 0.15 M NaCl of pH 5.5; together with pH 7.4 phosphate-buffered saline. The epigallocatechin gallate composition resulted in an IL-1 reduction of 28% based on a sample size of six. This was a significantly different response from the PBS + protease and bile acid insult (applying a Student's t-test with a $p<0.05$). These results were also subjected to the statistical outlier analysis.

In yet another set of EPIDERM skin culture experiments, the additive effect of extracted botanical actives and natural clay compounds for reducing the irritation response of the skin was elucidated. Green tea extract was selected as a representative extracted botanical active for testing. LAPONITE, available from Southern Clay Products Incorporated of Gonzales, Texas is a synthetic natural clay that was selected as representative of natural clays. The experiments were conducted according to the protocol previously described. The results are reported in Table 4. below.

Table 4.

Test Composition	Mean Reduction of Interleukin-1 Alpha (percentage)	Viability (percentage)
0.25% LAPONITE synthetic natural clay	70% (5)	106%
0.5% LAPONITE synthetic natural clay	79% (5)	106%
0.4% Green Tea Extract	41% (5)	113%
0.8% Green Tea Extract	77% (5)	113%
0.25% LAPONITE synthetic natural clay & 0.4% Green Tea Extract	104% (4)	117%
0.5% LAPONITE synthetic natural clay & 0.8% Green Tea Extract	124% (5)	119%

The number of replicates is indicated in parentheses. As with the other EPIDERM skin culture results, these results were subjected to the statistical outlier analysis. Statistical analysis using the student's t-test showed that each of the test compositions performed statistically better than the control (Phosphate-buffered saline + protease control). Further, statistical analysis showed that the two test compositions in which the synthetic natural clay and extracted botanical active were combined performed statistically better than either the synthetic natural clay or the extracted botanical active by themselves. These results show that extracted botanical actives and natural clays do not interfere with each other's ability to reduce the irritation response of the skin when the skin is exposed to biological-type insults. Further, the results show that extracted botanical actives and natural clays have an additive effect on reducing the irritation response.

An experiment was run examining the antioxidant activity of a green tea extract (DRAGOCO) in phosphate-buffered saline, PBS (pH 7.4) with and without suspended LAPONITE synthetic clay as measured by the ABTS chemical assay (Randox Laboratories Ltd., Diamond Road, Crumlin, Co. Antrim, United Kingdom, BT29 4QY). The method involved incubating a sample of ABTS (2,2'-Azino-di-[3-ethylbenzthiazoline sulphonate]) with a peroxoidase (metomyoglobin) and hydrogen peroxide (in stabilized form) to produce the radical cation ABTS*+. The radical cation formed is blue-green in color and stable at 734 nm in an aqueous system such as PBS. The concentration of antioxidant in the sample is measured as a reduction in color at 734 nm using a UV-vis spectrophotometer relative to a control value taken prior to adding substrate (time 0). The reduction in absorbance is directly related to the antioxidant activity. Readings are taken at three and six minutes and the level of antioxidant determined relative to a buffer control plus substrate at each time point.

The results were as follows. Green tea (original concentration 0.4%, diluted in assay to 0.006%) shows excellent antioxidant activity, inhibiting 100% of radical formation at 3 and 6 minutes. The addition of LAPONITE synthetic clay (original concentration 0.25%, diluted in assay to 0.004%)) with green tea extract (original concentration 0.4%) did not effect the antioxidant activity of the green tea extract when compared to the extract alone (concentration at 0.4%). These data indicate that clays can be combined with botanical antioxidants to provide additive skin health benefits (anti-irritant and antioxidant activities).

In a different series of experiments, the ability of compositions of the invention to inhibit enzyme activity was evaluated. The activity of various enzymes is associated with biological insults and when such enzymes are brought into contact with the skin, either because of a biological insult or otherwise, they are believed to have a detrimental effect on the integrity of the skin. Therefore, if the compositions of the invention have an inhibitory effect on such damaging enzymes, the compositions provide a benefit to the skin barrier and to skin health in general.

More specifically, compositions of the invention were evaluated for their inhibitory effect on porcine pancreatic trypsin in solution. Porcine pancreatic trypsin from Sigma Chemical of St. Louis, Missouri was prepared at a concentration of 1600 ng/ml in 100 mM Tris-HCL pH 8.0-buffer. Twenty-five microliters of the porcine pancreatic trypsin was added to the wells of a NUNC IMMUNO clear 96 well plate. The wells also contained 150 l of 100 mM Tris-HCL pH 8.0 buffer and 25 l of a test composition diluted as necessary in PBS. After a fifteen minute incubation at room temperature, the reaction is initiated by adding 50 l of a 5 mM solution of chromogenic trypsin substrate (N-benzyl-arginine-p-nitroanalide (BAPNA)) to each of the wells. The BAPNA is prepared at 50 mM in neat dimethylsulfoxide and diluted in water to a 5mM working stock solution. In order to measure the progress of the reactions, optical density measurements were taken at 405 nm every 20 seconds (after a two minute delay) for 10 minutes with a THERMOMAX Microplate Reader (Molecular Devices, Sunnyvale, CA). The concentration of test composition that inhibits 50% of the trypsin activity (IC_{50}) was determined. The degree of trypsin inhibition measured for various extracted botanical actives of compositions of the invention is reported in Table 5. Below. The IC_{50} value is based on a dilution of the liquid stock botanical. The actual concentration of the botanical/salt compositions is not known except for those compositions available in solid form. For the solid forms, stock concentrations in PBS can be accurately made up.

Table 5.

Extracted Botanical Active in Test Composition	Trypsin Inhibition (IC_{50})
Echinacea	0.005% (v/v)
Yucca Glauca	0.0125% (v/v)
Willow Herb	0.001% (v/v)
Spirulina	Hydrolysis greater than PBS control
Licorice	>0.5% (v/v)
Strontium Chloride	>0.5% (w/v)
Epigallocatechin gallate (component of green tea)	0.00002% (w/v)

The botanicals examined in Table 5. above are available from the following sources: *Echinacea purpurea* (Purple Coneflower), Bio-Botanica, Incorporated (Hauppauge, New York); Yucca Glauca extract, Brooks (South Plainfield, New Jersey); Canadian Willow Herb, Fytokem Products Incorporated (Saskatchewan, Canada); Spirulina, Bio-Botanica Incorporated (Hauppauge, New York); Licorice (Herbasol Extract Liquorice), Cosmetochem AG (Steinhausen/Zug, Switzerland). The Strontium Chloride and Epigallocatechin gallate were purchased from Aldrich (Milwaukee, Wisconsin) and Sigma Chemical Company, St. Louis, Missouri, respectively. These data indicate that *Echinacea purpurea* (Purple Coneflower), Yucca Glauca, Canadian Willow Herb and the green tea component (epigallocatechin gallate) are effective at reducing trypsin activity in solution.

While the invention has been described in detail with respect to the specific aspects thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these aspects. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.